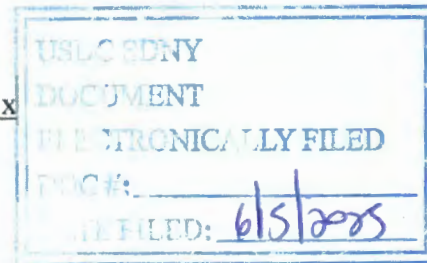


**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**



UNITED STATES OF AMERICA, et al., *ex rel.*
URI BASSAN,

Plaintiffs,

-against-

15 Civ. 4179 (CM)

OMNICARE, Inc.,

Defendant.

UNITED STATES OF AMERICA,

Plaintiff,

-against-

OMNICARE, INC. and CVS HEALTH CORP.,

Defendants.

**DECISION AND ORDER DENYING CVS HEALTH CORPORATION'S
RESERVED MOTION FOR DIRECTED VERDICT OF DISMISSAL**

McMahon, J.:

On April 25, 2025, this Court issued a written decision ("April 25 Opinion"), reserving judgment on the Motion for a Directed Verdict/Judgement as a Matter of Law made by Defendant CVS Health Corporation ("CVSHC"). Dkt. No. 756. CVSHC moved pursuant to Fed. R. Civ. P. 50 at the close of the Government's case, and again at the close of all the evidence. The Court reserved to give the jury the opportunity to weigh in on the Government's argument that CVSHC had "caused" its downstream subsidiary,¹ Defendant Omnicare, Inc. ("Omnicare"), to file false or

¹ Omnicare was directly acquired by CVS Pharmacy, Inc. ("CVS Pharmacy"), which is itself a subsidiary of CVSHC.

fraudulent claims with Government-sponsored health care plans, in violation of the False Claims Act. *Id.* at 22-23. The Government's theory was that CVSHC, as a party to a certain Corporate Integrity Agreement signed on October 11, 2016, ("CIA"), assumed the obligation to insure that Omnicare's prescription drug dispensing practices at long-term care facilities ("LTC facilities") comported with the law, but failed to direct Omnicare to correct its long-standing and well-known practice of dispensing non-controlled prescription drugs at certain types of LTC facilities without having obtained a valid prescription under state law.

The jury concluded that the Government had proved its theory of falsity, as well as knowledge and materiality. The jury further concluded that CVSHC had caused Omnicare to file a total of 1,016,039 false or fraudulent claims after its acquisition of Omnicare on August 18, 2015.² The jury concluded, however, that CVSHC's conduct did not cause the Government to suffer any damages. *See* Jury Verdict Sheet for CVSHC, at 2.

The jury having delivered a verdict against CVSHC, the Court must now resolve CVSHC's argument that the claims against it should have been dismissed at the close of Plaintiff's case – or again at the close of all evidence. CVSHC moved for directed verdict on two grounds: because it is a holding company with no employees or business other than owning its subsidiaries, and because the Government's evidence amounts to nothing more than conduct (or lack of conduct) that has been held insufficient to make out a False Claims Act violation on the part of a non-submitting party in other cases. CVSHC argues that Omnicare managed its own dispensings following the acquisition – a fact that no evidence disputes – while CVSHC, a holding company

² The Government had sought to make CVSHC liable for a total of 3,215,652 claims – essentially every false claim that Omnicare filed following the acquisition – but the jury obviously (and correctly) concluded that CVSHC could not possibly have failed to correct its new subsidiary's practice *immediately* after acquisition.

that conducted no pharmacy operations, could not have directly participated in the submission of Omnicare's false and fraudulent claims, as required to impose liability under the False Claims Act.

I have concluded that the Motion for a Directed Verdict should be DENIED because the Government's evidence demonstrates more than the type of conduct or lack of conduct that has been held insufficient in other False Claims Act cases – none of which, as I pointed out in the April 25 Opinion, has facts that precisely mirror the facts of this case.

LEGAL STANDARD FOR DIRECTED VERDICT

The Court may grant judgment as a matter of law under Fed. R. Civ. P. 50 “only when ‘a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue.’” *Cash v. Cnty. of Erie*, 654 F.3d 324, 333 (2d Cir. 2011) (quoting Fed. R. Civ. P. 50(a)(1)).³ Such a motion “may be granted only if the court, viewing the evidence in the light most favorable to the non-movant, concludes that a reasonable juror would have been *compelled* to accept the view of the moving party.” *Id.* (internal quotation marks omitted) (emphasis in original).

DISCUSSION

The first thing to get out of the way is the argument that, as a holding company that does not conduct any pharmacy operations, CVSHC cannot be held liable for causing Omnicare's False Claims Act violations. As I noted in the April 25 Opinion, two things are indisputably true.

First, unless the corporate veil is pierced, parent companies are not automatically liable for the misdeeds of their subsidiaries. *United States v. Bestfoods*, 524 U.S. 51, 61 (1998). In this case,

³ The standard for judgment as a matter of law at the close of evidence is the same as the standard for summary judgment. *See Piesco v. Koch*, 12 F.3d 332, 341 (2d Cir. 1993).

the Government has made no effort to pierce the corporate veil between CVSHC and Omnicare and abjured any intention to do so. *See* Dkt. No. 89, at 27. Therefore, the actions of Omnicare cannot be attributed to CVSHC, and CVSHC can only be held liable if its own conduct somehow facilitated the filing of false claims by Omnicare.

Second, holding companies do not get a pass on liability simply because they are holding companies. There are indeed circumstances in which a parent company that engages in no business operations could nonetheless be held liable for “causing” False Claims Act violations.

As is often the case, it is easier to say what those circumstances are not than to define what they are.

If the only evidence in the case were that CVSHC owned Omnicare, it would not be enough to hold CVSHC liable under the False Claims Act. *See Bestfoods*, 524 U.S. at 61 (“It is a general principle of corporate law deeply ingrained in our economic and legal systems that a parent corporation (so-called because of control through ownership of another corporation’s stock) is not liable for the acts of its subsidiaries.”) (internal citation omitted).

If the only evidence in the case were that CVSHC integrated Omnicare into its overall corporate structure – including its compliance structure and operations – it would not be enough to establish liability.⁴ *See, e.g., United States ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 514 (E.D. Pa. 2016) (Even where a defendant has “benefitted from [a subsidiary] financially, . . . [has] knowledge of [a subsidiary’s] practices and . . . [has] overlapping employees, managers or officers, such connections are too far removed to establish direct involvement in a

⁴ I make a specific point about this because the Government argued during its closing that the fact that Omnicare’s independent compliance department was effectively eliminated after it was acquired by CVS Pharmacy (directly) and CVSHC (indirectly) – and that its compliance operations became part of the overall integrated “CVS Health” compliance function – was evidence that could be used to hold CVSHC liable for causing Omnicare’s False Claims Act violations. That integration, however, is a legally insufficient basis on which to hold CVSHC liable for causing Omnicare to file false and fraudulent claims. Were the evidence such that this was the only basis on which CVSHC could have been found liable, I would readily grant the motion.

scheme subject to FCA liability.”); *United States ex rel. Schaengold v. Mem'l Health, Inc.*, 2014 WL 6908856, at *11 (S.D. Ga. Dec. 8, 2014).

If the only evidence in the case were that CVSHC exercised the type of normal, ordinary course oversight over a subsidiary that one would expect a parent corporation to exercise, that, too, would not be enough to sustain a verdict against CVSHC. *See, e.g., United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 245 (3d Cir. 2004) (“[M]ere awareness that another may, or even has, chosen to make [a false] claim does not alone constitute causing a false claim to be presented.”) (internal citations omitted); *United States ex rel. Nedza v. Am. Imaging Mgmt., Inc.*, 2020 WL 1469448, at *5 (N.D. Ill. Mar. 26, 2020).

And if the only evidence were that CVSHC owned Omnicare and had signed a corporate integrity agreement that implemented a general set of principles on the parent and its subsidiaries, that, too, would be insufficient. *See, e.g., Bastidas v. Good Samaritan Hosp.*, 2014 WL 1022563, at *7 (N.D. Cal. Mar. 13, 2014) (granting a motion to dismiss claims asserted against a parent company, despite the fact that the parent “implemented a Corporate Integrity Agreement, involving the distribution of a Code of Conduct . . . to all its subsidiaries”); *United States ex rel. Polukoff v. St. Mark's Hosp.*, 2016 WL 1449219, at *2 (M.D. Tenn. Apr. 13, 2016).

In this case, the Government argues that CVSHC can be held liable for causing its subsidiary, Omnicare, to violate the False Claims Act because of its own conduct – specifically, its failure to live up to affirmative obligations that CVSHC undertook when it signed the CIA.

Let’s take a deep dive into that argument and see what it requires – and of whom.

A. The “CVS Health” Corporate Integrity Agreement (GX-1503)

1. *The Parties to the CIA*

The Corporate Integrity Agreement (GX-1503) was entered into between “CVS Health Corporation and its subsidiaries” (collectively denominated as “CVS Health”) and the Office of the Inspector General of the Department of Health and Human Services (“OIG-HHS”), in October 2016.

The CIA, for all its prolixity and complexity, is far from a model of precise contract-drafting in one particular respect. That has to do with its indiscriminate use of the term “CVS Health.”

“CVS Health” is a defined term in this contract. It encompasses, not just CVSHC, but the parents and all of its subsidiaries – some of which have nothing to do with the provision of pharmacy services. (Aetna Health Insurance, for example, is a subsidiary of CVSHC, providing insurance, not pharmacy services; CVS Real Estate is another subsidiary, it deals with surplus real estate.⁵)

I have carefully read through the CIA multiple times. It certainly appears that at least some of the references to “CVS Health” in the document were intended to relate only to CVSHC. For example, there is a reference to the “Chief Executive Officer of CVS Health” in the CIA, at Section III.A.1. While this is a reference to a single person, each subsidiary of CVSHC has its own CEO, and they are not necessarily all the same person. Similarly, there is a reference to “the Board of Directors of CVS Health” at Section III.A.1.c. While CVSHC and every subsidiary has its own

⁵ See CVS Health Corp. Exhibit 21.1, Subsidiaries of the Registrant (Form 10-K) (SEC filed Feb. 12, 2025), <https://d18rn0p25nwr6d.cloudfront.net/C1K-0000064803/69ae70d3-3fe0-44a0-b601-f21026f8a49a.pdf>.

Board of Directors, this reference is to a single board, not to the many boards that surely exist across the CVS Health enterprise.

Furthermore, despite the broad definition of “CVS Health,” a provision in the Preamble of the CIA exempts from the CIA’s obligations and prohibitions every subsidiary of CVSHC except Omnicare “unless the CIA specifically states otherwise.” This provision, taken alone, makes perfect sense. The “Term and Scope of the CIA” is limited to CVSHC’s institutional pharmacy services operations (“IPS Operations”). *See* GX-1503, § II.C.1. Omnicare – and only Omnicare, among all of CVSHC’s many subsidiaries – engages in IPS Operations. So, it would make no sense to subject CVSHC’s other subsidiaries to the various IPS-related compliance and reporting provisions of this particular agreement. That interpretation is confirmed by my reading of the CIA, which reveals no provision “specifically stating” that any subsidiary of CVSHC other than Omnicare is subject to any of the contract’s substantive provisions at issue in this lawsuit. The annual reports and certifications required by the CIA are only submitted by the Chief Compliance Officer of “CVS Health” (the Chief Compliance Officer for the entire enterprise) and representatives of Omnicare.⁶ *See* GX-1503, § V.B-C. And the list of managerial employees who are required by the CIA to submit certifications of compliance to OIG-HHS each year does not include any persons in their capacity as employees of any CVSHC subsidiary other than Omnicare – not even CVS Pharmacy, Omnicare’s direct parent. *See* GX-1503, §III.A.5.

There is, however, the unfortunate fact that the CIA contains literally hundreds of references throughout its texts to the obligations of “CVS Health.” If that definition qualifies as “the CIA[’s] specifically stat[ing] otherwise,” then the verbiage used by the drafter would seem to render the express exemption for subsidiaries other than Omnicare meaningless.

⁶ Chief Compliance Officer for IPS Operations, Omnicare’s President, and Omnicare’s Chief Financial Officer.

But such a reading is utterly inconsistent, not only with the express exemption, but with the rest of the terms of the CIA. The only way to read the contract so that every provision of the agreement is meaningful is to conclude that, the general definition notwithstanding, (1) the subsidiaries of CVSHC other than Omnicare are not bound to comply with the provisions of the CIA unless some specific statement so provides, and (2) the definition of “CVS Health” does not qualify as “specifically stat[ing] otherwise.”

So, the only components of “CVS Health” that are indisputably bound by all of the relevant provisions of the CIA are CVSHC and Omnicare.

Moreover, even if my reading of the contract is incorrect, and if the drafter’s indiscriminate reference to “CVS Health” cancels the exemption for other subsidiaries in the Preamble, it remains indubitably the case that CVSHC was a party to the CIA and was bound by certain obligations thereunder.

2. Relevant Terms of the CIA

The purpose of the CIA was to promote compliance with statutes, regulations and written directives of Medicare, Medicaid and all other Federal Health care programs. Its principal provisions require “CVS Health” to continue and beef up its existing corporate compliance program.⁷

This “beefing up” included appointing both an IPS Chief Compliance Officer and IPS Compliance Committee (Section III.A.1 and 3); making sure that both the Chief Compliance

⁷ “CVS Health represents that it has implemented a compliance program (‘Compliance Program’) that includes, among other things, a Chief Compliance Officer and a Compliance Committee responsible for compliance oversight.” GX-1503, Preamble.

Officer and the IPS Chief Compliance Officer are high level employees of “CVS Health”⁸ (Section III.A.1); imposing special compliance obligations on the members of the “Board of CVS Health” concerning Omnicare’s IPS Operations (Section III.A.4); enhancing compliance training at Omnicare (Section III.A.5); imposing a variety of internal review obligations (Section III.F) and submitting initial and periodic reports and certifications of compliance (Section V).

All parties agree that the immediate impetus for the CIA and its enhanced compliance program was not the drug dispensing practices that are the subject of this lawsuit. Rather, the CIA grew out of conduct of Omnicare that was the subject of a prior *qui tam* action – one that predated Omnicare’s acquisition by CVS Pharmacy, and that alleged a far more prosaic violation of the False Claims Act by Omnicare, namely, violations of the federal Anti-Kickback Statute.⁹ As a result, most of the corporate integrity provisions in the CIA – including almost all of its compliance and oversight provisions – deal quite explicitly with kickbacks, their prevention and detection.

For example, the CIA required “CVS Health” to develop a Risk Assessment and Internal Review Process (Section III.G), but only relating specifically to “Arrangements,” a defined term that has to do solely with kickbacks (Section II.C.2). It required “CVS Health” to develop written standards relating to compliance with the Anti-Kickback Statute and the Stark Law, as well as the Corporate Integrity Obligations relating to those statutes, which are set forth in Section III.D. *See* GX-1503, § III.B. And it required “CVS Health” to establish a financial recoupment program that would cause “Covered Executives” to forfeit their compensation if involved in “significant

⁸ CVSHC has no employees (*see infra* at 14), so here the reference to “CVS Health” necessarily includes CVSHC’s subsidiaries.

⁹ For a confirmatory reference to this in the record, *see, e.g.*, GX-428, at OMNICARE-USAO 01086037.

misconduct” – a term defined in Appendix C as relating only to “Arrangements” (and hence to violations of the Anti-Kickback Statute or the Stark Law).

Moreover, as consideration for “the obligations of CVS Health” under the CIA, the Government agreed to refrain from taking certain actions against Omnicare and two other specified subsidiaries (NCS Healthcare, LLC and NeighborCare, Inc.) for “Covered Conduct” – a term defined in Paragraph F of the 2014 Omnicare Settlement Agreement. *See* GX-1503, Preamble.¹⁰ The term “Covered Conduct” could not possibly refer to the conduct that was the subject of this lawsuit because the allegations relating to Omnicare’s “rollover/cycle fill” program and its failure to obtain valid prescriptions under state law prior to dispensing non-controlled medications to residents of certain LTC facilities were not on the radar screen of HHS or the U.S. Department of Justice in 2014. Those allegations did not surface until June 2015, when Mr. Bassan filed his *qui tam* lawsuit.

There is, however, one brief section of the CIA that goes beyond kickbacks and encompasses other elements of Omnicare’s IPS Operations. Section III of the CIA is entitled “Corporate Integrity Obligations,” and Section III.E thereunder reads as follows:

Accurate Prescription Drug Labeling and Dispensing Systems and Procedures

Within 150 days after the Effective Date [of the CIA], CVS Health shall create systems and procedures reasonably designed to ensure the accurate labeling, tracking, dispensing, and billing of the drug name and manufacturer to the Federal health care programs of prescription drugs dispensed or used in connection with the IPS Operations. These systems and the procedure shall include, but are not limited to, the following:

1. tracking patient prescription drug information, including information about what specific drug, manufacturer, strength, and dosage was provided

¹⁰ I could not find the 2014 Omnicare Settlement Agreement that is referenced in the CIA among the evidence in this case. I do know, however, that it does not relate to the dispensing of controlled substances without valid prescriptions, because that relates to a settlement reached with HHS in 2012 – a matter I kept out of evidence at the trial of this case. *See* Dkt. No. 675. I thus deduce that the 2014 Settlement Agreement must relate to kickback allegations against Omnicare, not to anything in the 2012 settlement (which is nowhere referenced in the CIA).

to each individual patient, for the purpose of identifying patients impacted by recalls, market withdrawals, and safety alerts; and

2. establishing and implementing a schedule of routine audits of the Automated Label Verification system and any other automated prescription labeling and dispensing system used in IPS Operations to ensure accurate prescription drug labeling, tracking, dispensing and billing to the Federal health care programs.

For the most part, Section III, like the rest of the CIA, has nothing to do with the issues in this lawsuit. Nothing in the Government's complaint in this action attacked any Automated Label Verification system or addresses the tracking of prescription information for the purpose of identifying patients impacted by recalls and safety alerts.

However, the text of Section III.E.2 includes a more general requirement that "CVS Health" establish and implement routine audits of "any other automated prescription labeling and dispensing system used in IPS Operations" in order to "ensure accurate prescription drug...dispensing and billing to the Federal health care programs." The dispensing programs known as OmniDX and OASIS fall literally within that provision, as does the requirement, enshrined in law, *see* 21 U.S.C. § 353(b)(1), that prescription drugs be dispensed only as authorized by valid prescriptions.

This is the language in the CIA on which the Government's theory of liability hangs. Lest there be any doubt about this, in her closing argument, counsel for the Government said the following:

Ms. Mainigi got up here and told you that there's no possible way that CVS Health Corporation could have done anything in this case because it's basically a holding company and doesn't have any operations. And that that is undisputed evidence because Mr. Moffatt testified to it.¹¹ But you were here when I asked Mr. Moffatt questions about [a document not specified, likely GX-427]. And he admitted that what it said was that CVS Health Corporation is an integrated pharmacy services company. The company currently

¹¹ Mr. Thomas Moffatt's testimony that CVSHC is a holding company, and that it conducts no operations itself, is undisputed. None of the evidence to which the Government cites contravenes that statement.

maintains two operating business segments. Retailers LTC and Pharmacy Services. And it goes on to identify David Falkowski, our own David Falkowski, as SVP and Chief Compliance Officer of CVS Health Corporation. This is in connection with the CIA that involves Omnicare. It is in connection with the CIA that CVS Health Corporation reported the very issues that have come up in this trial. It reported them in a risk tracker that said it was related to the CIA.

This is CVS Health Corporation's participation in this case....when you have the power to stop something, when you promise that you will stop it, when you point out how it could be stopped and you choose not to do it, you have caused every false claim that flows from that choice.

Tr. 4142-43 (emphasis added).

3. *Duties of the Chief Compliance Officer Relevant to this Lawsuit*

The principal CVSHC actor identified by the Government as having facilitated Omnicare's filing of false and fraudulent claims is Mr. David Falkowski, Senior Vice President and Chief Compliance Officer for "CVS Health."¹² Section III.A.1 of the CIA contains the following language regarding the obligations of the Chief Compliance Officer:

The Chief Compliance Officer.....[is] responsible for, without limitation . . . overseeing all compliance matters related to CVS Health's IPS Operations; . . . developing, implementing, and enforcing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements; . . . making periodic (at least quarterly) reports regarding compliance matters relating to the IPS Operations directly to the Board Committee (defined below) of the Board of Directors of CVS Health, and shall be authorized to report on such matters to the Board Committee at any time. Written documentation of the Chief Compliance Officer and Compliance Officer for IPS Operations' reports to the Board Committee shall be made available to OIG upon request; . . . monitoring the day-to-day compliance activities engaged in by CVS Health related to the IPS Operations as well as for any reporting obligations created under this CIA; . . . reviewing and addressing the findings made and internal audits conducted as part of the Risk Assessment and Internal Review Process required by Section III.G; and . . . reviewing and addressing the Financial

¹² Under Section III.A.1 of the CIA, "Prior to the Effective Date, CVS Health appointed an employee to serve as its Chief Compliance Officer and shall maintain a Chief Compliance Officer for the term of the CIA." This is, of course, one of those indiscriminate uses of the term "CVS Health" that has dogged us throughout the trial of this case. However, because the CIA also requires the appointment of a separate "Chief Compliance Officer for IPS Operations," we know that the "Chief Compliance Officer" is not concerned solely with the operations of Omnicare but plays a broader role in the "CVS Health" empire.

Tracking Report of Arrangements created as part of the Risk Assessment and Internal Review Process required by Section III.G.

Once again, nearly all of these responsibilities have nothing to do with the issues in suit here. For example, the Risk Assessment and Internal Review Process required by Section III.G of the CIA concerns solely the identification and addressing of “risks associated with Arrangements” – a term that is limited to kickback-related conduct and not anything at issue in this lawsuit. *See* GX-1503, § II.C.2 (defining “Arrangements”). Similarly, the financial tracking program referenced in Section III.G relates solely to items carrying with them the potential for kickbacks. And most of the certifications required of the Chief Compliance Officer (as well as the Chief Compliance Officer for IPS Operations and the President of Omnicare) relate specifically to those anti-kickback provisions.

However, the Chief Compliance Officer (together with two others) was required to certify certain things to the Government annually that do touch upon the matters in suit. Principally, and the focus of the Government’s arguments at trial, Mr. Falkowski was required to certify compliance with Section III.E of the CIA, in the following terms:

to the best of his/her knowledge, CVS Health has implemented procedures reasonably designed to ensure the accurate labeling and dispensing of prescription drugs related to IPS Operations as required in Section III.E

GX-1503, § V.C.3.d (emphasis added).

Mr. Falkowski was also required to certify annually that “to the best of his/her knowledge, except as otherwise described in the report, “CVS Health” is in compliance with *all of the requirements of this CIA.*” GX-1503, § V.C.3.a (emphasis added). “All of the requirements of the CIA” include, not only the requirements of Section III.E relating to the accurate dispensing of prescription drugs, but also an obligation to report certain “Reportable Events” to OIG-HHS

pursuant to Section III.M, and to provide OIG-HHS with an annual summary of all such Reportable Events for the preceding year. *See* GX-1503, § V.B.23. The term “reportable events” includes “a substantial IPS Overpayment” (Section III.M.1.a), which means “the amount of money CVS Health’s IPS Operations have received in excess of the amount due and payable under any Federal health care program requirements” (Section III.L.1). That definition encompasses the overpayments found by the jury to have been made to Omnicare for false and fraudulent claims in violation of the False Claims Act.¹³

Section III.M.1.b identifies as a “Reportable Matter” any “matter involving IPS Operations that a reasonable person would consider a probable violation of criminal, civil or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.” These same adjudicated violations of the False Claims Act unquestionably involve “a matter involving IPS Operations that a reasonable person would consider a...violation of...civil or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.” GX-1503, § III.M.1.b.

B. The Evidence Relevant to the Verdict Against CVSHC

1. The CVSHC Corporate Structure

The undisputed evidence is as follows:

CVSHC is a publicly-traded holding company. It has a Board of Directors and officers, but no employees; its officers are employed by various subsidiary corporations. *See* Tr. 2581-82.

The only business CVSHC conducts relates to issuance of debt securities, holding the securities of its subsidiaries, and complying with the requirements imposed on publicly-traded

¹³ The Government made absolutely nothing of this during the trial; it is, however, apparent from the face of the CIA.

companies by the Securities Exchange Commission (SEC) and related entities. Tr. 2595. It does not engage in pharmacy operations, or in any business operations whatsoever. Tr. 2581-82. CVSHC had no role in dispensing medications and never itself filed a claim for reimbursement with the Government. Tr. 2586-87.

The “CVS Health logo” is used by the integrated pharmacy services operations conducted by certain subsidiaries of CVSHC as their “enterprise brand.” *See* Tr. 2588. The trademark itself is owned by CVS Pharmacy. *See* Tr. 2588.

The retail pharmacy, institutional pharmacy, pharmacy benefits management (“PBM”), and prescription drug plan operations that are carried out under the trade name “CVS Health” are conducted by various subsidiaries of CVSHC, not by CVSHC itself. *See* Tr. 2588. For example, the retail and institutional pharmacies and prescription drug plans operate under the umbrella of CVS Pharmacy, Omnicare’s direct parent; the PBM operations under the umbrella of CVS Caremark, LLC.; insurance under the umbrella of Aetna.

2. Compliance Within CVSHC

Prior to the Effective Date of the CIA, CVSHC had implemented a corporate-wide compliance program. GX-1503, § III.A.1, and named Mr. Falkowski, an employee of its subsidiary CVS Pharmacy, as its corporate-wide Chief Compliance Officer. Mr. Falkowski is “the Chief Compliance Officer for CVS Health” as defined in the CIA. Tr. 2613. Mr. Falkowski is also the Chief Compliance Officer for CVS Pharmacy. Tr. 2585.

CVS Pharmacy ran the corporate-wide compliance operations of CVSHC for the parent and all of its subsidiaries. Tr. 2587. However, each business line under CVS Health had its own compliance department, which reported to Mr. Falkowski. Tr. 2613. Mr. Falkowski in turn reported to the President of CVSHC. Tr. 2620. Omnicare thus had its own compliance officers. The IPS

Chief Compliance Officers required by the CIA to be appointed to oversee Omnicare's IPS Operations were Ms. Cara Zemenak, succeeded by Ms. Elizabeth Haley. Tr. 2590. Both were employees of Caremark, LLC, another CVSHC subsidiary. Tr. 2590-91.

3. CVSHC's Knowledge of the Issues in Suit

Prior to CVS Pharmacy's acquisition of Omnicare, Omnicare had knowledge of the issues in this suit:

- Omnicare employees had identified "rollover/cycle fill" prescribing of non-controlled substances in certain LTC facilities as a potentially serious compliance issue for Omnicare. *See, e.g.*, GX-28; GX-61, at OCRSDNY00064261; GX-62; GX-99; GX-134, GX-145, GX-153.
- Relatedly, Omnicare employees had identified the failure to obtain prescriptions that complied with relevant state law as a potentially serious compliance issue. *See, e.g.*, GX-1, GX-31, GX-36, GX-37, GX-91, GX-178, GX-204, GX-205.
- Mr. Bassan, the relator in this case, had identified and escalated these compliance issues internally: to Matt Massey, the general manager of Mr. Bassan's pharmacy, Tr. 109; to Jody Goppelt and Jodi Jordan, within Omnicare's IT department, Tr. 110; and finally, to Scott Huhn, the regional compliance officer at Omnicare, Tr. 113.
- Several states, including California, New York, Missouri, Texas, Nevada, Utah, Ohio and Arizona, had communicated with, investigated, cited, warned or sanctioned Omnicare for prescribing drugs without having prescriptions that met the requirements of those states' laws. *See, e.g.*, GX-1606A and GX-1606B. *See also* GX-8-2, GX-8-3, GX 48-4, GX-37, GX-47, GX-49-1, GX-49-2, GX-67, GX-71, GX-72, GX-75, GX-168, GX-1300, GX-1302-1, GX-1303-1, GX-1305-1, GX-1317, GX-1325, GX-1326, GX-1327, GX-1328. In addition, Mr. Bassan brought the matter before the New Mexico Board of Pharmacy, which sent an advisory letter to Omnicare just days after it was acquired by CVSHC. *See* GX-1330.

In July 2016 – after CVS Pharmacy's acquisition of Omnicare and shortly before the signing of the CIA in October 2016 – members of the CVS Pharmacy "Risk Assessment" team identified (i) cycle fill/rollover dispensing to assisted living and other non-skilled facilities and (ii)

the acceptance of chart orders/physician order sheets (“POS”) as potential compliance issues.¹⁴ See GX 413; GX-413-1. These items were added to the risk tracker in response to a Government inquiry into these issues – an inquiry occasioned, as it happens, by the filing of Mr. Bassan’s *qui tam* action. See Tr. 1730. These items were designated highest priority, and the creators of the risk tracker suggested possible solutions to address them. In the case of cycle fill/rollover, the proposal was to update the dispensing computer programs, and, in the case of chart order and POS acceptance, the proposal was to survey state laws on prescription requirements. GX-413-1.

A subsequent risk tracker internal to CVS Pharmacy was circulated on January 10, 2017 – three months after the CIA was signed – again reflecting the dispensing and chart order issues as high-priority risks requiring resolution by January 30, 2017. See GX-228; Tr. 1755-59. The same potential problems were also identified in a CIA-specific risk tracker circulated two months later, on March 28, 2017. See GX-229; GX-229-1; Tr. 1770-73. These risk trackers again identified the steps that should be taken to address these issues: for cycle fill/rollover, an update to system programming to ensure that prescriptions did not automatically rollover without authorization by pharmacy personnel according to state or federal regulation, and, for chart orders, a state-by-state review of relevant law to ensure that Omnicare pharmacies were in compliance with all local requirements – compliance with which is mandated under Medicare, Medicaid, and TRICARE. See GX-229-1. Of note, the CIA-specific risk tracker identified these issues as being “indirectly” related to the obligations undertaken by CVSHC and Omnicare in Section III.E of the CIA. See GX-229-1.

¹⁴ This tracker did not include any complaints from Mr. Bassan who had filed his lawsuit on June 1, 2015, two and a half months before the acquisition.

Following the acquisition, Omnicare employees continued to call attention to the cycle fill/rollover compliance issue and the steps that the members of the compliance teams deemed necessary to address them. Communications to that effect were circulated to various officers and employees of CVS Pharmacy. *See* GX-4; GX-209; GX-210; GX-235. Among the recipients of such communications was Mr. Falkowski. *see* Tr. 2603. Mr. Falkowski was informed of these risks and about the steps that members of the compliance team deemed necessary to address them. *See* GX-4; GX-209; GX-210; GX-235. For example, Mr. Falkowski was copied on an email dated March 6, 2017 (GX-4), to which was attached a document entitled “Operations Compliance Update” dated February 22, 2017 (GX-4-1). The document indicated, under the heading “Facility Location Code Clean Up,” that the rollover issue had been corrected in late 2016 by locking down the ability of local pharmacies to code Assisted Living Facilities (“ALFs”) as Skilled Nursing Facilities (“SNFs”):

In December [2016], system controls were put in place that locked down the facility location codes after initial entry of the facility. The reason for this was that it was identified during regulatory reviews that pharmacies were going into these fields and flipping it from an ALF to a SNF so they could force the label and order out the door. With the lock down they are no longer able to do this. These fields are what prompts the system not to allow filling after an order depletes refills or expires.

GX-4-1, at CVSBASSAN00001728.

But subsequent “Operations Compliance Update” dated March 28, 2017 (GX-416-1) indicated that the lock down discussed a month earlier had been reversed as a “business decision”:

When we [presumably Omnicare] began receiving the edited reports from the pharmacies, we immediately started getting emails from the billing department that claims were rejecting due to the place of service code. A business decision was made to revert back to the original set up until a complete review could be performed. Changing the location code impacts reimbursement so standardization of these codes is being reviewed.

GX-416-1, at OCBASSAN01242446.

Mr. Greg Sciarra, Vice President of International Operations at Omnicare, testified that the officers of CVSHC would have been tracking compliance issues. *See* Tr. 1861-63. Indeed, one email admitted into evidence proves that Mr. Falkowski was copied on—at least—the February 2017 Operations Compliance update. *See* GX-4-1. Furthermore, Mr. Falkowski had certification responsibilities under the CIA that would have required him to inform himself of CIA-related compliance matters, of which this was one. Viewing the evidence most favorably to the Government, it is fair to infer that Mr. Falkowski was aware that the correction made in late 2016 to the dispensing system was undone in early 2017.

For quite some time, this compliance remained the subject of study rather than action. A May 2017 email from Mr. Zakaria Elyamani, a senior manager in the “shared services” of CVS Pharmacy, indicates that this issue was to be the subject of discussion within his business compliance unit at a meeting scheduled for May 9, 2017. *See* GX-181; GX-181-1. The trail of email and other communications relating to the issues in suit goes fairly cold thereafter. However, the record reveals that the issues raised in the risk trackers as early as April 2016 (GX-209, at OCRBASSAN01599435) – shortly after Omnicare was acquired by CVS Pharmacy – continued unresolved for quite some time. While Mr. Elyamani’s meeting to discuss “these issues” was to be held in May 2017, neither the cycle fill/rollover IT fix nor the study of state laws to ascertain whether using chart orders violated state regulations had been completed a year and a half later, according to a risk tracker that was circulated in September 2018. *See* GX-173-7. This September 2018 risk tracker indicated that potential fixes had been submitted in June 2016, but had not been implemented tow years later (“Awaiting timeframe for system enhancements, Timeline for developing policy, training and communication...”). *See* GX-173-7, at OCRBASSAN01475787.

However, on two occurrences – March 2, 2017 and February 1, 2018 – Mr. Falkowski, acting in his capacity as Chief Compliance Officer of CVSHC certified to OIG-HHS, pursuant to Section V.C.3.d of the CIA that, “CVS Health has implemented procedures reasonably designed to ensure the accurate . . . dispensing of prescription drugs related to the IPS Operations as required in Section III.E [of the CIA].” *See* GX-427, at OMNICARE-USAO-01087327; GX-428, at OMNICARE-USAO-01086092. (The cycle fill/rollover and chart order issues were nowhere listed as Reportable Events.) Yet at the time these certifications were submitted the changes needed to address these compliance issues had either been implemented and reversed or they not yet been implemented – though what needed to be done had long since been identified.

C. The Motion for Directed Verdict is Denied

Viewing the evidence most favorably to the Government (as I must), I conclude that CVSHC’s Motion for a Directed Verdict must be DENIED.

CVSHC is plainly a party to the CIA and is bound by its terms. The Government declined to make an agreement only with Omnicare; it wanted Omnicare’s ultimate parent to be a party. As a result, the CIA imposes obligations on CVSHC, and does not exempt CVSHC from compliance with those obligations (unlike its non-Omnicare subsidiaries, which are expressly exempt from most obligations under the CIA). Mr. Moffatt, the Vice President, Secretary and Senior Legal Counsel of Corporate Services for CVS Pharmacy, admitted during his testimony that CVSHC undertook affirmative obligations pursuant to the CIA. *See* Tr. 2603-04. Those obligations included all of the various provisions discussed above that relate to the oversight of the dispensing practices of Omnicare, which are the IPS Operations that fell within the “Terms and Scope” of the CIA.

The CIA required CVSHC, through the office of its Chief Compliance Officer, to, *inter alia*, develop, implement, and enforce policies, procedures and practices designed to ensure

compliance with the federal healthcare program requirements; make periodic reports regarding compliance matters directly to the Board Committee of the Board of Directors of CVSHC; monitor the day-to-day compliance activities engaged in by the CVS Health enterprise related to IPS Operations; and review and address the findings made and internal audits conducted related to risk assessment under the CIA. *See* GX-1503, § III.A.1. Additionally, the CIA required “Certifying Employees” (of which Mr. Falkowski was one) to annually certify that: “To the best of [his] knowledge, the [department] of CVS Health that deals with IPS Operations is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement.” GX-1503, § III.A.5.

The undisputed evidence is to the effect that CVSHC, which had no employees of its own, carried out any obligations it had under the CIA through the good offices of its subsidiaries – principally its subsidiary (and Omnicare’s direct parent), CVS Pharmacy. It is undisputed that CVS Pharmacy ran the compliance operation on behalf of the integrated “CVS Health” enterprise – an enterprise that consisted of many separate corporations in different lines of business. And it is undisputed that an employee of CVS Pharmacy (Mr. Falkowski) was the Chief Compliance Officer through whom the reporting and certification responsibilities under the CIA were effected. As a result, CVSHC insists that it cannot be found to have “caused” Omnicare to file false claims with the Government – because corporations other than CVSHC did or failed to do the things that the Government claims facilitated those filings.

But the fact that an employee of CVS Pharmacy was tasked with carrying out certain corporate obligations does not mean that the person acted *only* on behalf of CVS Pharmacy. The jury was instructed, without objection, that the actions of “officers, directors, *agents* or employees” of a corporation could bind a corporation. *See* Tr. 4217 (emphasis added). CVS Pharmacy, like all

CVSHC subsidiaries except Omnicare, was exempt from obligations under the CIA. CVSHC, however, was not exempt. So even if Mr. Falkowski was wearing his hat as an employee of CVS Pharmacy when acting as Chief Compliance Officer of “CVS Health” – as Defendant contends – a reasonable trier of fact could conclude that CVS Pharmacy was acting as the agent of CVSHC when Mr. Falkowski performed the obligations imposed on that corporation by the CIA. Indeed, a reasonable trier of fact could hardly conclude otherwise.

Even if CVS Pharmacy was not exempt – which is to say, even if the repeated references to “CVS Health” throughout the text of the CIA constituted the “specific statements” needed to negate the express exemption found in the Preamble of the CIA – a reasonable trier of fact could still have concluded that CVSHC, which was manifestly NOT exempt from the CIA, had responsibilities that had to be carried out, and that CVS Pharmacy (and Mr. Falkowski, an employee thereof) acted, or failed to act, not only on behalf of CVS Pharmacy, but on behalf of CVSHC, in carrying out those obligations.

And how did CVSHC’s failure to live up to its obligations under the CIA facilitate the filing of false and fraudulent claims by Omnicare? The Government’s theory was simple: CVSHC “caused” the filing of false and fraudulent claims by certifying (falsely) that Omnicare’s dispensing systems complied with the law, even though it was aware of deficiencies in those systems – deficiencies with clear legal implications – yet allowed its subsidiary to dilly-dally for two years without making the necessary corrections.

Now, is this enough for CVSHC to incur liability? I believe that it is. This is something more than mere corporate ownership, awareness, oversight, or integration into the larger CVS Health enterprise. If anything, it is akin to the “knowing ratification of [a subsidiary’s] prior policy of submitting false claims by rejecting recommendations to bring [the subsidiary] into regulatory

compliance,” that was discussed in *United States ex rel. Martino-Fleming v. South Bay Mental Health Centers*, 540 F.Supp.3d 103, 130 (D. Mass May 19, 2021) (citation and internal quotations marks omitted). In that case, the corporate parents at issue were a private equity firm and its subsidiary (collectively, “H.I.G.”), whose employees occupied a majority of board seats at another company, C.I.S., which in turn owned health centers alleged to have submitted false claims. *Id.* at 111-12. An officer of C.I.S. developed a report raising concern that false claims were being submitted by the subsidiary health centers in 2014 and brought that report to the attention of H.I.G. employees in 2016 (two years later) as “still relevant” because working group recommendations to address the issue had not yet been implemented. *Id.* at 114. On causation, Judge Saris observed that,

two years after the [working groups’] recommendations were presented, [the H.I.G. employees] received a report showing that the relevant recommendations were not implemented. There is sufficient evidence in the record that by virtue of its members’ participation in the C.I.S. Board, H.I.G. had the power to fix the regulatory violations which caused the presentation of false claims but failed to do so.

Id. at 130. On those grounds, Judge Saris denied the defendants’ motion for summary judgment with respect to H.I.G.’s role in causing the submission of false claims. *Id.*

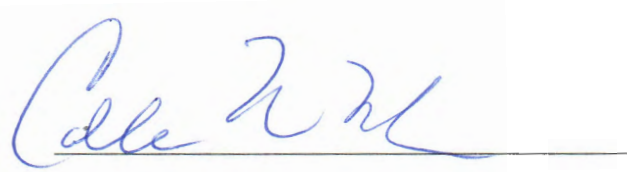
I need not substitute the actors in our case to make the analogy clear. Like, Judge Saris I do not believe that an intermediary entity – in our case, CVS Pharmacy – insulates CVSHC from liability. There is sufficient evidence from which a jury might reasonably find that CVSHC, acting through its agent, “knowingly ratified” the conduct of Omnicare sufficient for CVSHC to incur liability under the False Claims Act.

CONCLUSION

For the reasons stated above, Defendant CVSHC’s Motion for a Directed Verdict is DENIED.

This constitutes a written opinion. The Clerk is directed to remove the motion at Dkt. No. 741 from the Court's list of open motions.

Dated: June 5, 2025

A handwritten signature in blue ink, appearing to read "Calle R. M.", is written over a horizontal line.

U.S.D.J.